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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, Defendant.	**DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT** Case No. 2:20-cv-374 (SMJ) Pl.'s Motion: Jan. 7, 2021 Def.'s Cross-Motion: Jan. 28, 2021 Without Oral Argument

Jeremy Olsen claims a right to reimbursement by Medicare for continuous glucose monitor supplies. Acting for the Secretary of Health and Human Services, the Medicare Appeals Council denied coverage in accordance with CMS Ruling 1682-R. Mr. Olsen now seeks judicial review. But the Secretary's decision that continuous glucose monitors accurate enough to replace a blood glucose monitor would be covered by Medicare, while less accurate devices would not, was neither

arbitrary nor unlawful. Mr. Olsen's motion for summary judgment should therefore be denied, and the Secretary's cross-motion granted.

BACKGROUND

A. Medicare Part B and CMS Ruling 1682-R

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary of Health and Human Services by the Centers for Medicare & Medicaid Services (CMS). Part A of the Medicare statute "covers medical services furnished by hospitals and other institutional care providers." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5). Medicare Part B "is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services" and "durable medical equipment," among other things. *Id.* (citing 42 U.S.C. §§ 1395j to 1395w-4).

The statutory definition of durable medical equipment (DME), codified at 42 U.S.C. § 1395x(n), "includes iron lungs, oxygen tents, hospital beds, and wheelchairs . . . used in the patient's home," as well as "blood-testing strips and blood glucose monitors for individuals with diabetes" among other specified items. A regulation elaborates that durable medical equipment is "equipment[] furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 C.F.R. § 414.202. Such equipment is only covered by Medicare Part B if it is "reasonable and necessary for the diagnosis or treatment" of a beneficiary's "illness or injury." 42 U.S.C. § 1395y(a)(1)(A). And the Secretary has the authority to "establish and implement quality standards for suppliers of items and services" covered by Medicare Part B. *Id.* § 1395m(a)(20).

In 2017, the Secretary issued a CMS Ruling—a "statement of policy or interpretation" that is "binding on all CMS components," 42 C.F.R. § 401.108; *see id.* § 405.1063(b)—on the subject of Part B coverage for continuous glucose monitors. CMS Ruling 1682-R (Jan 12, 2017), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf. CGMs measure glucose levels in the interstitial fluid between patients' cells, not in their blood. *Id.* at 6. The CMS Ruling said that some continuous glucose monitors were accurate enough to replace a blood glucose monitor, because they could be used to

guide treatment decisions "such as changing one's diet or insulin dosage based solely on the readings of the CGM." *Id.* at 7. These highly accurate CGMs are covered as durable medical equipment under the terms of the CMS Ruling, *id.* at 8, but less accurate devices are not, *id.* at 15.

B. Medicare Coverage Determination and Claim Appeal Process

To seek reimbursement for the cost of a continuous glucose monitor or anything else, "a Medicare Part B beneficiary must submit a claim for an 'initial determination' of whether 'the items and services are covered or otherwise reimbursable.'" *Porzecanski v. Azar*, 943 F.3d 472, 475–76 (D.C. Cir. 2019) (quoting 42 C.F.R. § 405.920); *see* 42 U.S.C. § 1395ff(a)(1). "Initial coverage determinations are made by" Medicare administrative contractors hired by the agency "to manage the preliminary claims administration process." *Porzecanski*, 943 F.3d at 476. "If the contractor denies the beneficiary's claim," he may "obtain a 'redetermination' from the same contractor." *Id.* (citing 42 U.S.C. § 1395ff(a)(3)(A); 42 C.F.R. § 405.940). "If unsuccessful, the beneficiary can seek 'reconsideration' by a 'qualified independent contractor' who is wholly independent of the initial determination contractor." *Id.* (citing 42 U.S.C. § 1395ff(c)(1)–(2); 42 C.F.R. § 405.960).

If the beneficiary remains unsatisfied, subject to a minimum amount-in-controversy requirement, "he can request a hearing before an administrative law

judge (ALJ)." *Id.* (citing 42 C.F.R. § 405.1000); *see* 42 U.S.C. § 1395ff(b)(1)(E). After that, he can seek review by the Medicare Appeals Council, *see* 42 C.F.R. § 405.1100, which makes the final decision for the Secretary, *id.* § 405.1130. If the beneficiary is not satisfied with the decision of the Council, he may then seek judicial review within 60 days, 42 U.S.C. § 405(g), subject to another amount-in-controversy requirement, *id.* § 1395ff(b)(1)(E).

C. Procedural Background

Jeremy Olsen sought reimbursement by Medicare Part B for a continuous glucose monitor transmitter and sensors that he received in 2018. The initial determination and redetermination were unfavorable, AR 150, 160–61, 163, as was the decision on reconsideration, AR 124. Mr. Olsen sought review by an administrative law judge, who found his continuous glucose monitor to be a covered device. AR 40–43.

The Medicare Appeals Council undertook review on its own motion. AR 29. The Appeals Council found that CMS Ruling 1682-R required it to deny coverage. AR 12–22. Mr. Olsen sought timely judicial review, and venue was transferred to this district.

ARGUMENT

A. The Appeals Council's decision was substantively valid.

Following CMS Ruling 1682-R, the Medicare Appeals Council determined that Mr. Olsen's continuous glucose monitor was not sufficiently accurate to be covered as durable medical equipment under Medicare Part B. Under the terms of that Ruling, CGMs are only covered if they are accurate enough to be "used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM." CMS Ruling 1682-R at 7. Less accurate CGMs are not covered. This determination is neither arbitrary, contrary to statute, nor "non-sensical" (as Plaintiff would have it, *see* Mot. at 3).

To begin with, it is not contrary to statute because a continuous glucose monitor is not a "blood glucose monitor," which the Medicare statute defines as durable medical equipment. 42 U.S.C. § 1395x(n). As CMS Ruling 1682-R explains, CGMs measure glucose levels in the interstitial fluid between patients' cells, not in their blood. CMS Ruling 1682-R at 6. Congress has determined that "blood-testing strips and blood glucose monitors for individuals with diabetes" should be covered as durable medical equipment. 42 U.S.C. § 1395x(n). "[B]lood-testing strips" are the supplies for a patient's "blood glucose monitor," a device that monitors glucose levels in the patient's blood. Continuous glucose monitors simply do not do so. Instead, they measure something correlated with the

level of glucose in a patient's blood (that is, the level of glucose in their interstitial fluid). To the extent that there is any ambiguity in the statutory phrase, the Secretary's interpretation—that blood glucose monitors must monitor blood glucose levels, not the levels of glucose in other bodily fluids, even if they are correlated to blood glucose levels—is plainly reasonable and therefore entitled to this Court's deference. *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984).

Nor was it arbitrary or otherwise unlawful for the Secretary to distinguish between continuous glucose monitors that are accurate enough to be "used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM," which are covered under the terms of CMS Ruling 1682-R (at 7), and less accurate devices, which are not covered. The Secretary's position is that continuous glucose monitors are only covered as durable medical equipment by Medicare Part B if they are accurate enough to guide treatment decisions. *Id.* at 8. Less accurate devices, whose readings must be confirmed by using a blood glucose monitor, are not covered. *Id.* at 15. This is not an arbitrary distinction. There are more accurate and less accurate CGMs on the market, and it is entirely reasonable for the Secretary to encourage the use of the more accurate devices. Although this might well have been accomplished through the establishment of quality standards under 42 U.S.C. § 1395m(a)(20), the

Secretary has instead drawn this reasonable distinction through an interpretation of the Medicare statute and its implementing regulations.

The Secretary's view has been that the "medical purpose" of a CGM is to enable a beneficiary to make treatment decisions, and that less-accurate CGMs do not serve that medical purpose. *See* CMS Ruling 1682-R at 9 ("The medically necessary function of a glucose monitor is to inform the patient about their glucose level so that they can make diabetes treatment decisions such as changing their diet or insulin dosage."). The Secretary has sometimes described the less-accurate devices that do not serve this medical purpose as "adjunctive" or "precautionary." *See* CMS Ruling 1682-R at 6–7, 14. But the core of the Secretary's position has been that certain CGMs do not effectively serve the medical purpose of that device. CMS Ruling 1682-R sets out a coverage standard under which more accurate CGMs are covered, and less accurate CGMs are not. That determination is reasonable, lawful, and entitled to deference from this Court.

Nonetheless, the Secretary is currently reconsidering his position on whether devices such as the continuous glucose monitor at issue here should be considered durable medical equipment within the meaning of the Medicare statute and regulations. He recently published a notice of proposed rulemaking which would, if finalized, "classify CGM systems . . . as DME" whether or not they can be used to make treatment decisions on the basis of their readings alone. 85 Fed. Reg.

70,358, 70,403–04 (Nov. 4, 2020). The comment period closes on January 4, 2021; the Secretary will apprise the Court if and when a rule is finalized.

B. The procedural claim should be dismissed, has been waived, and could not lead to the only relief sought here.

Plaintiff suggests that CMS Ruling 1682-R was issued in violation of the Medicare statute's notice-and-comment requirement, *see* 42 U.S.C. § 1395hh(a)(2), and that the decision of the Appeals Council was therefore tainted by its reliance on a procedurally invalid CMS Ruling. In doing so, Plaintiff appears to press his claim under 5 U.S.C. § 706(2)(D), which should be dismissed for the reasons set forth in the Secretary's pending motion to dismiss.

Moreover, as another district court has recently held, an objection to the procedural validity of CMS Ruling 1682-R is waived if it is not raised before the Appeals Council, which it was not here. *Zieroth v. Azar*, 2020 WL 5642614, at *3 (N.D. Cal. Sept. 22, 2020) ("[T]he Court finds the procedural challenge [to CMS Ruling 1682-R] asserted by Zieroth was waived" when it was not raised before the agency.). *See Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) ("A party forfeits arguments that are not raised during the administrative process.").

And even if the Court determines that this procedural claim should not be dismissed and was not waived, the Court need not reach it unless the Court first upholds the substantive validity of the Secretary's decision. The procedural

argument is a fallback position that would not lead to the principal relief that plaintiff is seeking: an order that the Secretary approve Mr. Olsen's claim for benefits. If the Secretary's final decision improperly relied on a procedurally invalid CMS Ruling, then the remedy is a remand so that the Secretary can decide Mr. Olsen's claim without reference to the disputed Ruling. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 201 (1947) ("After the remand was made, therefore, the Commission was bound to deal with the problem afresh, performing the function delegated to it by Congress.")). Because a procedural error would not give this Court license to make a *de novo* coverage determination itself, any procedural failing in the decision of the Medicare Appeals Council should not lead to a substantive reversal of the Secretary's coverage determination.

CONCLUSION

The Court should uphold the decision of the Medicare Appeals Council, enter summary judgment in favor of the Secretary, and deny Plaintiff's motion for summary judgment.

Respectfully submitted,

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